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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,928

07/29/2005

Michael Berthon-Jones

4398-427

8053

23117 7590 11/24/2008
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

11/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,928	Applicant(s) BERTHON-JONES ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 34-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed August 14, 2008. As directed by the amendment, claims 19-27 and 34 have been amended and new claims 43-44 have been added. Claims 1-18 & 29-33 have been cancelled as directed in applicants response filed April 4, 2008. Thus, claims 19-28 & 34-44 are pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 19-20, 22-23, 27, and 34-42 rejected under 35 U.S.C. 102(a) as being anticipated by Amarasinghe et al., (WO 02/45784).

Regarding claim 19, Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) including at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including at least one selected portion (12) provided to the main body, said selected frame portion being adjustable relative to the main body; and a cushion (16) provided to the frame, the cushion being structured to provide an interface with the patient (figure 2), wherein said at least one selected frame portion (12) is engaged with the cushion (by wrapping around the cushion as seen in figure 2) so that the cushion is adjustable (on and off of

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patient via straps connecting 12) in accordance with a position of said at least one selected frame portion relative to the main body (12), and said cushion, upon application of positive pressure, applying a force to the patient, said force being adjustable in accordance with 1) the position of said at least one selected frame portion relative to the main body for a given value of said positive pressure (via the tightening of the straps as positive air flow pressure increases); and/or 2) variations in the positive pressure (as the positive air flow is increase, the straps will tighten and when the air flow is decreased to straps will loosen).

Regarding claim 20, Amarasinghe discloses a mask assembly with at least one headgear connector portion provided to said at least one selected frame portion (15), said frame portion adapted to be movable in accordance with change in headgear strap tension to thereby adjust the force applied to the sides of the patient's nose and/or face in use (via adjusting the straps). See: figure 2.

Regarding claim 22, Amarasinghe discloses a mask assembly wherein the at least one selected frame portion includes a flexible member supporting the cushion (15 supports the cushion by wrapping around it when the straps are fitted around a users head). See: figure 2.

Regarding claim 23, Amarasinghe discloses a mask assembly with a main body (13) and the at least one selected frame portion (12) which are provided as two separate parts that are coupled to one another. See: page 6, line 27 –page 7, line 6 and figure 4.

Regarding claim 24, there is no structural limitation added to this claim. It is the examiner's position that the main body and the selected portion are moveable by a camming mechanism. Since a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact the mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism. Since the camming mechanism is not part of the claimed apparatus, and the main body and the at least one selected frame portion are deemed to be moveable by a camming mechanism, the apparatus disclosed by Amarasinghe meets the claim.

Regarding claim 27 Amarasinghe discloses a mask assembly with at least one selected frame portion that includes lateral sides (15) of the frame that are made of a flexible material. See: page 7, lines 21-27.

Regarding claim 34, Amarasinghe discloses a mask assembly (10) for application of non-invasive positive pressure ventilation to a patient, comprising: a frame (figure 4) including a main body (13) having at least one aperture (hole in 13) configured to receive a supply of breathable gas under pressure, said frame including a selected frame portion (12) provided to the main body, said selected frame portion being adjustable relative to the main body (it can be attached and detached from the 13); and a cushion provided to the frame (16), the cushion being structured to provide an interface with the patient (figure 2), wherein the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with the position of the selected frame portion relative to the main body, and wherein the selected frame portion

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includes each lateral side of the frame (15), and the selected frame portion is bendable to cause each lateral side of the frame to push against sides of the cushion (12 is a bendable metal).

Regarding claim 35, Amarasinghe discloses a mask assembly with a selected frame portion (12) that includes a flexible member (20) supporting the cushion. See: page 7, lines 8-20.

Regarding claim 36, Amarasinghe discloses a mask assembly wherein the main body is relatively stiffer than the flexible member. See: page 30, lines 29-30.

Regarding claim 37, Amarasinghe discloses a mask assembly with a main body (13) and a selected frame portion (12) that are provided as two separate parts that are coupled to one another. See: page 6, line 27 - page 7, line 6 and figure 4.

Regarding claim 38, Amarasinghe discloses a mask assembly wherein the selected frame portion (12) includes lateral sides of the frame (15) which are made of a flexible material (12 is a bendable metal).

Regarding claim 39, Amarasinghe discloses a mask assembly with a selected frame portion that is bendable about a longitudinal axis of the frame (12 is a bendable metal).

Regarding claim 40, Amarasinghe discloses a mask assembly with a selected frame portion (12) that includes side wing portions (15) which are movable relative to the main body to adjust the sides of the cushion (16).

Regarding claim 41, Amarasinghe discloses a mask assembly wherein each of the side wing portions are adjustable into a plurality of positions (12 which forms 15 is bendable).

Regarding claim 42, Amarasinghe discloses a mask assembly with a cushion that is adapted to provide a seal with the patient's nose (16 forms a seal with the user's face, which includes the user's nose).

Regarding claim 43, the at least one selected frame portion (12) is adjustable (it is a malleable wire that would deform the cushion with enough applied force) to deform the cushion to adjust the fit and/or seal of the cushion on the patient's face. See: figure 2.

Regarding claims 44, the selected frame portion (12) is adjustable (it is a malleable wire that would deform the cushion with enough applied force) to deform the cushion to adjust the fit and/or seal of the cushion on the patient's face. See: figure 2.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 and 34 above, in view of Gradon et al., (2003/0089373).

Amarasinghe discloses all the limitations of claim 21 except the knob to change the relative positioning between the main body and the frame portion.

Gradon teaches a knob (440) that is used to adjust the bridge member (430). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue the straps.

6. Claims 25-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784), as applied to claim 19 above, in view of Hellings et al., (5,975,079).

Amarasinghe discloses all the limitations of claims 25-26 and 28 except the cushion with an inflatable unit that adjusts the size of the nasal bridge and the element providing for multiple stiffening rates of the cushion .

Hellings teaches a mask that is curved and contoured around the mouth and nasal bridge with an inflatable cushion. The reference teaches applying the mask to a user's face and then inflating the cushion, to provide a pneumatic seal. See: col. 3, lines 48-65.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask disclosed by Amarasinghe by using an inflatable cushion as taught by Hellings, because of the reasonable expectation of obtaining a mask with a pneumatic seal while simultaneously alleviating orbital irritation and eliminating ocular pressure.

Regarding claim 28, the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.

Response to Arguments

7. Applicant's arguments filed August 14, 2008 have been fully considered but they are not persuasive.

8. In response to applicant's argument to the rejection of claims 19-20, 22-23, 27, and 34-42, and as applied to claims 43-44 which are rejected under 35 U.S.C. 102(a) as being anticipated by Amarasinghe et al., (WO 02/45784), the examiner respectfully disagrees.

Applicant argues that Amarasinghe does not disclose that the brace (12) is structured to engage the cushion (16) and that the at least one selected frame portion that is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body, however, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In the instant case, the brace (12) is a malleable wire that is engaged with a cushion (via strap and a shell) and the brace is easily maneuvered by hand and

Amarasinghe specifically shows portions (15) of brace (12) wrapping around the cushion (16) in figure 2. Therefore, the brace (12) is structured to engage the cushion (16) via shell (13) and tightening of the straps; and the tightness of the cushion would inherently be adjusted via the straps connected to brace (12).

Upon positive pressure being applied to the mask, a pressure differential would inherently be created and by the mask being strapped to a patient (figure 2) the cushion would inherently apply a force to the patient by virtue of it being strapped to the patient. This pressure applied to a patient would then either be increased or decreased by tightening or loosening of the straps connected to the brace (12).

Regarding applicants argument that Amarasinghe does not disclose the selected frame portion being bendable to cause each lateral side of the frame to push against sides of the cushion as recited in claim 34, the examiner respectfully disagrees.

Amarasinghe does teach the brace (12) as being bendable (page 3, [0041]) and the brace (12) surrounds the body of the mask with lateral projections at (15) of the brace.

9. Regarding applicants argument to the rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784) and further in view of Gradon et al., (2003/0089373), that claim 21 should be allowable because Gradon does not make up for the deficiencies in Amarasinghe, the examiner respectfully disagrees.

10. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,

208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As discussed above, Amarasinghe discloses all the limitations of claim 21, except the knob to change the relative positioning between the main body and the frame portion.

Gradon was used to teach the obviousness of using a knob that adjusts a bridge member and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue the straps.

11. Regarding applicants argument to the rejection of claims 25-26 and 28 under 35 U.S.C. 103(a) as being unpatentable over Amarasinghe et al., (WO 02/45784) and further in view of Hellings et al., (5,975,079) that claims 25-26 and 28 should be allowable because Hellings does not make up for the deficiencies in Amarasinghe, the examiner respectfully disagrees.

12. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As discussed above, Amarasinghe discloses all the limitations of claims 25-26 and 28 except the cushion with an inflatable unit that adjusts the size of the nasal bridge and the element providing for multiple stiffening rates of the cushion.

Hellings teaches a mask that is curved and contoured around the mouth and nasal bridge with an inflatable cushion. The reference teaches applying the mask to a user's face and then inflating the cushion, to provide a pneumatic seal and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask disclosed by Amarasinghe by using an inflatable cushion as taught by Hellings, because of the reasonable expectation of obtaining a mask with a pneumatic seal while simultaneously alleviating orbital irritation and eliminating ocular pressure.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lang et al., (2005/0211252) discloses a breathing mask with a frame.

15. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/

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Supervisory Patent Examiner, Art Unit 3771